

### **REMARKS**

In the Final Office Action ("FOA") of October 21, 2003, the Examiner withdrew from consideration newly submitted claims 24-28 as being directed to a non-elected invention. The Examiner also provided direction on how to effect drawing changes. Finally, the Examiner rejected claims 18-23 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 4,284,077 to Wagner ("Wagner").

Applicant has amended independent claim 18 to improve clarity and makes the following remarks. Applicant respectfully submits that the claims are patentable over the art of record. A notice of allowance is respectfully requested.

#### **Objection To Drawings**

In the Office Action ("OA") of March 13, 2003, the Examiner objected to the drawings for failing to show every feature of the invention specified in the claims, specifically the receptacle, rim and opening. The Examiner also objected to the drawings because reference characters "9" and "18" both point to the same structure in Figures 5 and 6.

In the response to the OA, Applicant submitted drawing corrections to overcome the drawing objections in the OA. However, apparently, the drawing corrections did not meet the formal requirements of 37 C.F.R. § 1.84. Accordingly, in the FOA, the Examiner requested drawing corrections that meet the formal requirements of 37 C.F.R. § 1.84.

Applicant now submits two sets of drawing sheets (i.e., a first set of three sheets with each sheet identified in the top margin as a "Replacement Sheet" and a second set of three sheets with each sheet identified in the top margin as an "Annotated Marked-up Drawing"). The three sheets of Annotated Marked-up Drawings include Figures 5, 6 and 7 and show the proposed changes, which are indicated in red ink and are enclosed within clouds. The three Replacement Sheets include Figures 5, 6 and 7 and replace the original sheets containing Figures 5, 6 and 7.

Figures 5, 6 and 7 have been changed so reference characters "9" and "18" now have separate leaders that point to the passage and cut-off valve, respectively. Figures 5 and 6 have been changed to include reference character "2," which is recited in the specification as

pertaining to the product reservoir and clearly indicated in Figures 1, 7 and 8 as filed. The words receptacle, rim and opening are no longer recited within the claims, though these features were clearly apparent in the figures as filed.

**Rejection under 35 U.S.C. § 102**

In the FOA, the Examiner rejected claims 18-23 under 35 U.S.C. § 102(b) as being anticipated by Wagner. A claim is anticipated only if each and every element as set forth in the claim is found in a single prior art reference. *MPEP* § 2131.

In response to Applicant's claims and arguments filed in response to the Office Action of March 13, 2003, the Examiner states, "[t]here are numerous locations in which the Applicant uses functional language and the Examiner interprets the language of the claims as functional for purposes of the rejection. If Applicant wishes to positively recite the language in order to give patentable weight to the instant application, Examiner encourages Applicant to do so." *FOA*, p. 4.

"[W]hen evaluating the scope of a claim, every limitation in the claim must be considered. Office personnel may not dissect a claimed invention into discrete elements and then evaluate the elements in isolation. Instead, the claim as a whole must be considered." *MPEP* § 2106, p. 2100-9, 2<sup>nd</sup> col..

"There is nothing inherently wrong with defining some part of an invention in functional terms. Functional language does not, in and of itself, render a claim improper." *MPEP* § 2173.05(g) .

**"A functional limitation must be evaluated and considered, just like any other limitation of the claim,** for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used." *MPEP* § 2173.05(g) (*emphasis added*). This position is consistent with Federal Circuit law. For example, a party urged the Federal Circuit to ignore the following functional limitation:

a pair of linear actuators mounted on said frame and connected to  
said levers for swinging said levers and thus tilting said cradle about its

pivots from said first position through a second position, wherein the pot is raised from the ground but held substantially level, to a third position wherein the pot is tipped by abutting an abutment on the cradle and is at least partially inverted to a dumping position.

*Kress Corp. v. Alexander Services, Inc.*, No. 97-1309, 1998 Westlaw 398819, \*\*2, \*\*3 (Fed. Cir. June 15, 1998) (unpublished). The Federal Circuit declined the party's request to ignore the functional language and said, "we have consistently held that all limitations of claims must be considered meaningful." *Id.* at \*\*3.

Thus, it is clear, per the Federal Circuit and the MPEP, that functional limitations must be evaluated and considered like any other claim limitation. Furthermore, claims are not to be dissected, but are to be considered as a whole. With this in mind, Applicant now compares independent claim 18 to Wagner, the cited art.

In Applicant's independent claim 18, the device is configured such that "abutting the suction chamber against the tissue of the patient causes the cut-off valve to open, which places the suction chamber and volume in fluid communication, thereby causing a state of reduced pressure within the suction chamber and bringing the tissue in contact with the dispensing means." Furthermore, in independent claim 18, the "state of reduced pressure" is created by "a piston pump comprising a cylinder, a piston, and a lock, wherein the rod displaces the piston within the cylinder to create a volume within the cylinder having a state of reduced pressure and the lock is adapted to lock the piston in place to maintain the state of reduced pressure."

As best understood from Figs. 1 and 2 of Wagner, to actuate the Wagner device, "the rim of the suction cup 6 is applied to the skin of a patient and the control knob 75 is activated." *Wagner, col. 6, ll. 1-2*. Wagner's control knob is a "hand-operated control knob 75." *Wagner, col. 4, ll. 63*. Thus, unlike the invention recited in Applicant's claim 18, Wagner's hand-operated control valve is not opened by "abutting the suction chamber against the tissue of the patient." Furthermore, Wagner discloses no way for inherently achieving this aspect of Applicant's independent claim 18.

Wagner's additional step of actuating the control valve by hand makes Wagner less advantageous as compared to Applicant's invention as recited in claim 18. This is because Wagner's additional step presents an additional anxiety hurdle to the injection (i.e., the user must overcome both the anxiety created by placing the Wagner device against the skin and the anxiety created by pushing Wagner's hand-operated control knob 75).

Again referring to Figs. 1 and 2 of Wagner, in activating the hand-operated control knob 75, "pressurized gas ... is applied ... into a nozzle 84 of a jet pump 89 thus creating an underpressure that is applied through a suction conduit 80 and the one-way valve 88 into the suction cup 6. Due to this under-pressure, the skin of the patient is sucked into the cup 6 and punctured by the cannula." *Wagner, col. 6, ll. 3-14*. Thus, unlike the invention recited in Applicant's claim 18, Wagner's jet pump-created underpressure (i.e., state of reduced pressure) is not created by "a piston pump." Furthermore, Wagner discloses no way for inherently achieving this aspect of Applicant's independent claim 18.

Applicant's invention as recited in claim 18 is advantageous over Wagner because Applicant's invention does not require Wagner's pressurized gas expense.

Because (1) functional limitations must be evaluated and considered, just like any other limitation of the claim, and (2) Wagner fails to explicitly or inherently anticipate each and every functional limitation recited in Applicant's independent claim 18 and its corresponding dependent claims, Applicant respectfully requests reconsideration and withdrawal of the anticipation rejections of claims 18-23. A notice of allowance is respectfully requested.

Respectfully submitted,

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"Annotated Marked-up Drawing"

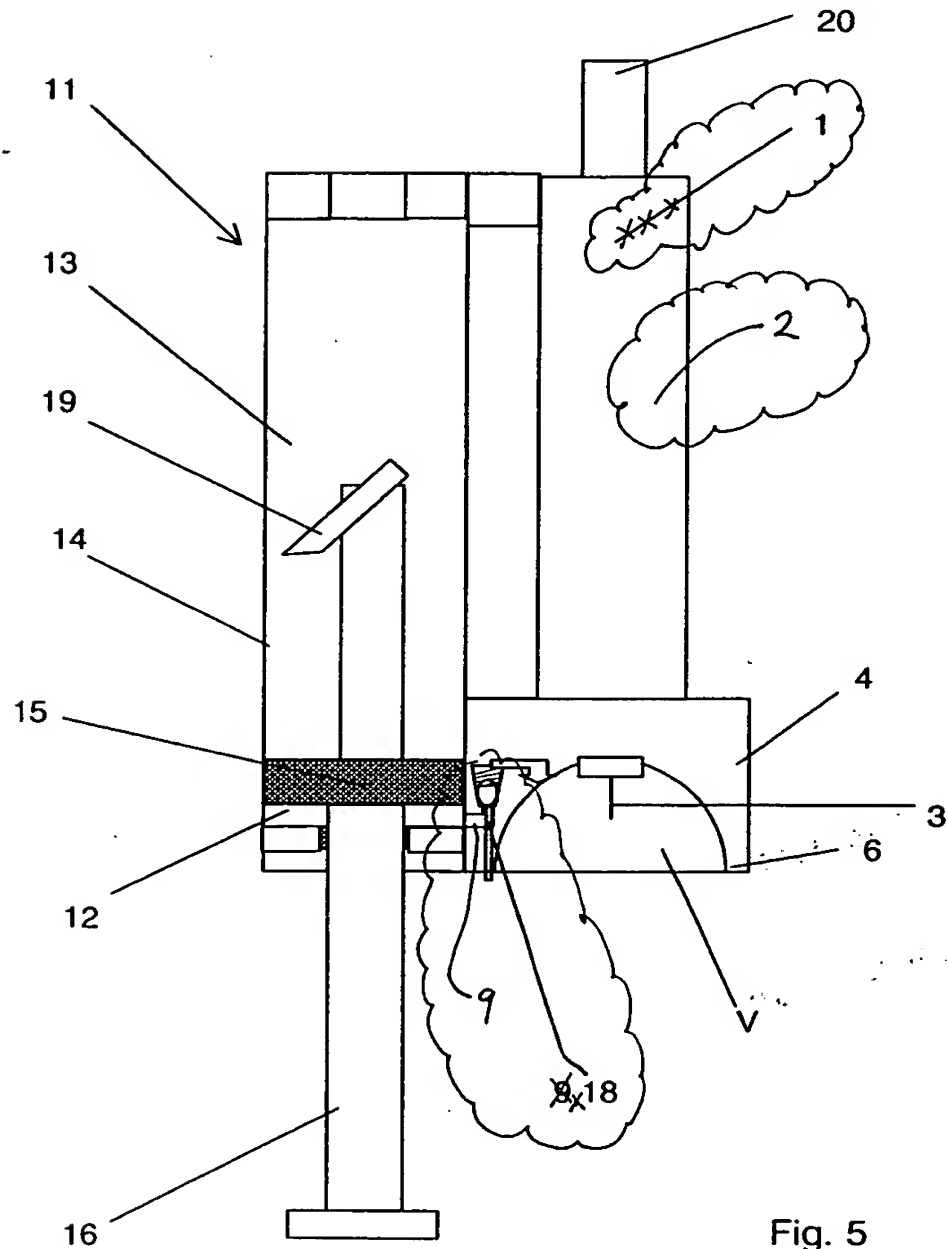


Fig. 5

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"Annotated Marked-up Drawing"

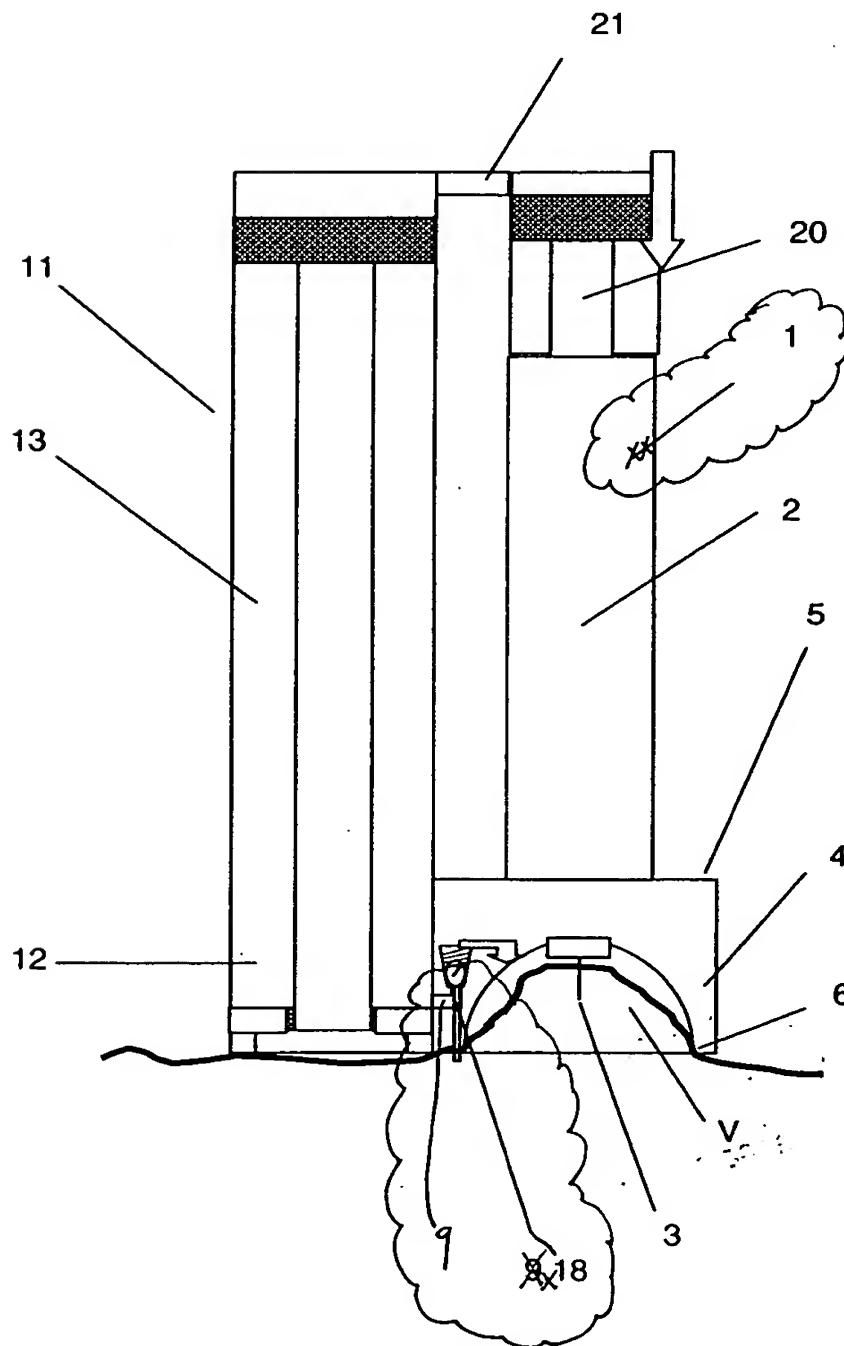


Fig. 7.